IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
NORTHERN DIVISION

UNITED STATES OF AMERICA ex rel. JONATHAN SAFREN, *Plaintiff/Relator*, v. ST. AGNES HEALTHCARE, INC., *Defendant*.	Case No. _____ **FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)** **JURY DEMANDED**

COMPLAINT

Plaintiff Dr. Jonathan Safren, by his attorneys, brings this action as a relator on behalf of the United States of America and hereby states as follows for his Complaint against Defendant St. Agnes Healthcare, Inc. ("St. Agnes"):

NATURE OF THE ACTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from St. Agnes' intentional submission of false claims to the government for reimbursement under the Medicare program and the Federal Employees Health Benefits Program (collectively, the "Federal Health Insurance Programs" or "FHIPs"), in violation of the False Claims Act, 31 U.S.C. § 3729 *et seq.* ("FCA"). This action involves a prototypical FCA violation in which St. Agnes knowingly overcharged the federal government by claiming reimbursement for services that were more extensive, and more expensive, than the services actually performed.

2. The Federal Health Insurance Programs pay a higher rate when a new patient makes an office visit to a physician (as compared to a return visit by an existing patient) in order

to compensate the physician for the additional time and effort needed to conduct an initial physical exam, take a comprehensive patient history, and diagnose the patient's condition.

3. The Centers for Medicare and Medicaid Services ("CMS") require health care providers to use Current Procedural Terminology Codes ("CPT Codes") formulated by the American Medical Association ("AMA") to designate the health care service for which the provider seeks reimbursement. Indeed, providers who submit bills for services under all of the Federal Health Insurance Programs are subject to this requirement.

4. CMS and the AMA have published guidelines regarding which CPT Code must be used for each service provided. Those guidelines mandate that a physician may not use the CPT Code for treating a "new" patient, and thereby seek a higher payment for the visit, if the physician has treated the patient within the previous three years.

5. In June 2011, St. Agnes acquired the practice of a group of twelve cardiologists who formerly were members of a private physician practice called MidAtlantic Cardiovascular Associates ("MidAtlantic"). The twelve cardiologists became employees of St. Agnes, and constituted its Maryland Cardiovascular Associates.

6. At that time, St. Agnes' Director of Compliance, Brenda Hammerbacher, acting in knowing violation of the governing CMS guidelines, directed the cardiologists to bill the next office visit made by each of their established patients under the CPT Code for a new patient visit, regardless of whether the patients had been seen by the physician in the previous three years.

7. Plaintiff-Relator Dr. Safren raised a concern at the meeting that Ms. Hammerbacher's instruction was improper, but Ms. Hammerbacher dismissed his concerns. The other cardiologists then reached a consensus to follow Ms. Hammerbacher's instruction. Dr.

Safren did not follow Ms. Hammerbacher's instruction, but other members of the Maryalnd Caridovascular Associates confirmed to Dr. Safren that they followed her instruction.

8. As a result of St. Agnes' fraudulent billing, the Federal Health Insurance Programs paid thousands of fraudulent claims for new patient visits for health care services rendered to existing patients.

9. Plaintiff-Relator brings this action pursuant to 31 U.S.C. § 3730(b)(1) and seeks a judgment pursuant to § 3729(a)(1) awarding three times the amount of damage the Government sustained as a result of St. Agnes' fraudulent claims for new patient visit reimbursements, imposition of the maximum civil penalty for each of St. Agnes' violations of the False Claims Act, and Relator's attorney's fees and costs.

PARTIES

10. Plaintiff-Relator Dr. Jonathan Safren is a citizen and resident of the State of Maryland. Dr. Safren was employed as a cardiologist by St. Agnes from June 3, 2011 to June 30, 2013. Dr. Safren personally witnessed events that are the subject of this complaint.

11. Defendant St. Agnes Healthcare, Inc. is a non-stock corporation organized and existing under the laws of the State of Maryland. St. Agnes operates an acute care general hospital in Baltimore, Maryland, and offers inpatient and outpatient services to patients. St. Agnes provides services to patients whose care is reimbursed through federal funds through the Medicare program and the Federal Employees Health Benefits Program. St. Agnes submitted to the Federal Health Insurance Programs the claims that are the subject of this Complaint.

JURISDICTION AND VENUE

12. This Court has personal jurisdiction over Defendant St. Agnes Health Care, Inc. as it is a corporation that is located and operates in the State of Maryland.

13. This Court has general federal question subject matter jurisdiction over Plaintiff-Relator's claims under the False Claims Act, 31 U.S.C. §§ 3729 et seq. pursuant to 28 U.S.C. § 1331. This Court also has jurisdiction pursuant to 31 U.S.C. § 3732, in which Congress specifically provided this Court with subject matter jurisdiction over actions brought under the FCA. There has been no statutorily relevant public disclosure of the allegations or transactions described in this Complaint under 31 U.S.C. § 3730(e).

14. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(1) and (c)(2), as Defendant St. Agnes resides in this judicial district as an entity with the capacity to sue and be sued in its common name under applicable law and is subject to this Court's personal jurisdiction. Venue also is proper pursuant to 28 U.S.C. § 1391(b)(2), as a substantial part of the events or omissions giving rise to the claims at issue occurred within this district.

FALSE CLAIMS ACT PROCEDURE

15. Plaintiff-Relator has made arrangements to file this Complaint under seal and to serve this Complaint along with the requisite written disclosure of material evidence and information upon the Government, but not upon St. Agnes, consistent with the requirements of 31 U.S.C. § 3730(b)(2).

16. Plaintiff-Relator voluntarily disclosed to the government the information on which the allegations or transactions in this case are based, including St. Agnes' fraudulent submission of claims for services provided to new patients when such patients were not new patients but were instead existing patients.

GENERAL ALLEGATIONS

I. Background

A. The Federal Health Insurance Programs

17. Medicare is a federally funded health insurance program primarily benefitting the elderly. Medicare was created in 1965 when Title XVIII of the Social Security Act was adopted.

18. Medicare Part A (the Basic Plan of Hospital Insurance) covers the cost of hospital inpatient stays and post-hospital nursing facility care. Medicare Part B (the Voluntary Supplemental Insurance Plan) covers the costs of physician services and certain other services. not covered by Part A. Physician services under Part B are reimbursed on a fee-for-service basis. This Complaint concerns services provided under Medicare Part B.

19. CMS administers Medicare but much of the daily administration and operation of the Medicare program is managed through contracts with private insurance companies that operate as fiscal intermediaries.

20. The Federal Employees Health Benefits Program provides more than $40 billion in health care benefits annually to federal employees, retirees, and their dependents. It was created by the Federal Employees Health Benefits Act of 1959 (the "FEHBA").

21. The FEHBA established an Employees Health Benefits Fund to pay for program expenses and put forth provisions for studies, reports, and audits.

22. In addition, the Federal Employees Health Benefits Program outlined the role of the Office of Personnel Management ("OPM"). By law, OPM has the authority to contract with insurers and to prescribe regulations to manage the program, among other duties.

B. The Methodology for Reimbursing Physician Services

23. The Healthcare Common Procedure Coding System ("HCPCS") is a standardized coding system designed to ensure that Medicare, Medicaid and other federal health care

programs pay for services rendered to patients in accordance with the level of resources necessary to provide such care.

24. In the case of physician services, the American Medical Association has compiled a list of thousands of Current Procedural Terminology Codes ("CPT Codes") that best reflect the services provided by physicians to their patients. The HCPCS system relies on the CPT codes for the coding of physician services.

25. Under HCPCS, a CPT Code is assigned a weight or value (called a Relative Value Unit or "RVU"). The payment level for any given procedure is then determined by multiplying the RVU value for the code times a conversion factor that takes into account regional and other variable cost factors.

26. When a physician's service is billed to a fee-for-service FHIP, the provider selects the CPT Code associated with the treatment. The HCPCS system then generates a payment amount based on the CPT Code that is paid to the provider.

C. Under The Billing Guidelines, Physicians May Not Submit a Claim for the Enhanced Payment Amount Associated with a Service Provided to a New Patient If They Treated That Patient Within the Previous Three Years.

27. There are five CPT codes that may be selected to bill for office or other outpatient visits for a new patient: CPT Codes 99201-99205. The five codes reflect an increasing level of patient severity, so that a 99201 code reflects low severity, 99203 moderate severity, and 99205 a high degrees of severity.

28. Corresponding to these codes, five similar codes may be used for an office or other inpatient visit for an existing or established patient: CPT Codes 99211-99215.

29. These two series of codes are effectively mirror images of one another, and describe patients with corresponding levels of severity and medical need. If a new patient with

particular medical condition has his office visit classified as 99203, the same patient with the same condition would have his visit classified as 99213 if he were an established patient.

30. The difference between the two series of codes is that in the case of new patients, a detailed history and detailed examination is required, and it is anticipated that physicians will spend additional time with the patient.

31. Thus, for example, in 2013, when Dr. Jeffrey Cole, a Maryland Cardiovascular Associates physician, provided health care services to a new cardiology patient of moderate severity, he would have been expected to use billing code 99203. He would have been expected to see the patient for 30 minutes, and would have been entitled to receive $111.38 in reimbursement. When he saw an existing patient with the same symptoms, he would have been expected to use billing code 99213. He would have been expected to see the patient for 15 minutes, and would have been entitled to receive $74.46 in reimbursement.

32. The enhanced payment associated with the CPT Codes for new patients is not intended to provide a bonus for physicians who change practice groups, or to the groups that acquire them. Instead, the enhanced payment is intended to ensure that when a physician sees a patient for the first time, the physician is reimbursed for the additional time spent on a comprehensive examination and history.

33. This common-sense interpretation is reflected in the established rules and definitions that govern use of the CPT codes, which limit the use of the new patient code to patients whom the billing physician has not seen in the previous three years. Thus, the definitions section in the AMA's 2011 CPT Manual, the operative manual governing the claims St. Agnes submitted in 2011, provides that:

> A new patient is one who has not received any professional services from the physician or another physician of the same specialty who belongs to

> the same group practice, within the past three years. An established patient is one who has received professional services from the physician or another physician from the same specialty who belongs to the same group practice, within the past three years.

34. That definition is repeated in a "Coding Tip" that appears prominently on the page of the CPT Manual describing the codes for outpatient services. Any billing professional who reviews the criteria for billing such services is reminded that a patient who has received professional services from a physician within the previous three years may not be billed as a new patient. A copy of the relevant page of the CPT Manual is attached as Exhibit A.

35. CMS similarly has adopted this definition and displayed it prominently. The "Frequently Asked Questions" section of the CMS website provides:

> What is the definition of "new patient" for billing evaluation and management (E/M) services?
>
> Interpret the phrase "new patient" to mean a patient who has not received any professional services, i.e., evaluation and management service or other face-to-face service (e.g., surgical procedure) from the physician or physician group practice (same physician specialty) within the previous three years.

36. The definition appears in other, more formal contexts as well. The Medicare Claims Processing Manual provides claims processing instructions for physician services, including when patient visits can be characterized as "new patients." That Manual defines a "new patient" to mean "a patient who has not received any professional services, i.e., E/M service or other face-to-face service (e.g., surgical procedure) from the same physician or physician group practice (same physician specialty) within the previous 3 years." Medicare Claims Processing Manual (Pub.100-04), Ch. 12 § 30.6.7.

37. CMS also has published an Evaluation and Management Services Guide. This Guide similarly provides (at p. 7) that:

> "[a] new patient is defined as an individual who has not received any professional services from the physician/non-physician practitioner (NPP) or another physician of the same specialty who belongs to the same group practice within the previous three years. An established patient is an individual who has received professional services from the physician/NPP or another physician of the same specialty who belongs to the same group practice within the previous three years."

II. St. Agnes Knowingly Billed the Federal Health Programs for Services to New Patients When The Physicians Provided Services to Established Patients.

A. St. Agnes Acquired the Maryland Cardiovascular Associates and Incentivized It to Maximize Billing.

38. Effective June 3, 2011, twelve cardiologists affiliated with Mid-Atlantic and practicing at the Seton Professional Building at 3449 Wilkens Avenue, Baltimore, MD, agreed to become employees of St. Agnes as members of the Maryland Cardiovascular Associates. The following cardiologists were included in the Maryland Cardiovascular Associates, and held the following duties upon inception:

Physician Name	Title	Duties
Albornoz, Martin	Co-Director of Interventional Cardiology Program	Interventional Call Coverage
Cole, Jeffrey		Administrative Cardiologist
Dua, Vineet		Administrative Cardiologist
Hillsley, Russell		Administrative Cardiologist
Ince, Carlos	Chief of the Section of Cardiology	Administrative Cardiologist
Kuhn, Frederick	Director of Non-Invasive Cardiology	Administrative Cardiologist
Plack, Raymond	Co-Director of Interventional Cardiology Program	Interventional Call Coverage
Plantholt, Stephen		Administrative Cardiologist
Safren, Jonathan		Administrative Cardiologist
Voss, Matthew		Interventional Call Coverage
Wang, David		Administrative Cardiologist
Winakur, Shannon		Administrative Cardiologist

39. The members of the Maryland Cardiovascular Associates entered into employment agreements that provided for an initial base salary of $400,000 per physician and a bonus payment for administrative services. The employment agreements also provided for a productivity bonus based on the amount of RVUs generated. (As described above, RVUs reflect the relative amount of work necessary to provide medical care.)

40. Under the employment agreements, if the total RVUs generated by the Maryland Cardiovascular Associates exceeded a certain amount, then a bonus pool would be generated from their billings from which the members of the Maryland Cardiovascular Associates would be compensated. The bonus pool in turn would be allocated to individual members of the Maryland Cardiovascular Associates based on their own levels of RVUs.

41. St. Agnes thus incentivized the members of the Maryland Cardiovascular Associates to increase their RVUs, both individually and as a group. When a Maryland Cardiovascular Associates physician billed an established patient under billing codes reserved for new patients, the physician was eligible to share in a portion of the enhanced fee that was generated by the mis-classification.

B. St. Agnes Director of Compliance Directed Members of the Maryland Cardiovascular Associates to Bill Established Patients as if They Were New and the Members Agreed.

42. The change in the legal status of Mid-Atlantic physicians from private practice members of Mid-Atlantic to Maryland Cardiovascular Associates employees of St. Agnes did not affect the physicians' relationship with their patients in any way. In fact, the change was effectively imperceptible to patients. The same cardiologists saw the same patients, in the same offices, with the same nursing staff, on the same schedule, and with access to the same patient records.

43. In late May 2011, the members of the Maryland Cardiovascular Associates met with Brenda Hammerbacher, Director of Compliance for St. Agnes. All of the physicians in the group were in attendance, and the meeting took place in the lunchroom of their office at 3449 Wilkens Avenue, Suite 300, Baltimore, Maryland 21229.

44. Ms. Hammerbacher is a Certified Professional Coder ("CPC"), with a certificate from the American Academy of Professional Coders. CPC certification is designed to ensure proficiency in physician-billing matters. To achieve certification, an applicant must demonstrate knowledge of topics including billing for health care services based on the CPT Codes.

45. Ms. Hammerbacher had approximately 20 years of experience in physician billing, and described herself as well-versed in compliance, coding and billing for multi-specialties including facility and physicians.

46. At that meeting in late May 2011, Ms. Hammerbacher advised the twelve cardiologists who were members of the Maryland Cardiovascular Associates that after the doctors became St. Agnes employees, they should treat the next visit of every patient they saw as a new patient visit, regardless of whether the doctor had seen that patient within the previous three years.

47. At the meeting, Dr. Safren expressed concerns that Ms. Hammerbacher's directions were not in compliance with the rules that governed billing for new patients.

48. No other member of the Maryland Cardiovascular Associates supported Dr. Safren's position. Instead, three or four members of the Maryland Cardiovascular Associates responded to Dr. Safren by arguing that billing for existing patients as if they were new patients would help the Maryland Cardiovascular Associates attain its productivity bonus, and that Dr.

Safren would benefit if he billed in this manner as well since the total productivity bonus, and his portion of it, would be greater.

49. Ms. Hammerbacher and the Maryland Cardiovascular Associates discussed the billing practice, and reached a consensus that the physicians would follow the directive and would bill the initial patient visit with the St. Agnes Maryland Cardiovascular Associates as a new patient visit, even if the physician had provided services to the patient within the previous three years.

C. The Maryland Cardiovascular Associates Doctors other than Dr. Safren Followed St. Agnes' Directive and Billed Existing Patients as "New."

50. Physician compensation and the potential bonus pool payment was a topic of significant interest to the members of the Maryland Cardiovascular Associates, and Dr. Safren spoke regularly about billing practices with other members of the Maryland Cardiovascular Associates. Through these conversations, Dr. Safren confirmed his understanding that the other members of the Maryland Cardiovascular Associates were applying the billing codes for new patients for the initial visit from patients they had seen in the previous three years.

51. In one instance, for example, in the early fall of 2011, Dr. Safren and four other members of the Maryland Cardiovascular Associates—Dr. Dua, Dr. Kuhn, Dr. Cole, and Dr. Plantholt—attended a lunch sponsored by a pharmaceutical company. At that lunch, Dr. Safren asked the other physicians whether they were following St. Agnes' instruction to bill existing patients as new patients. Each of those physicians confirmed to Dr. Safren that they were complying with Ms. Hammerbacher's instruction to bill existing patients as new patients.

52. Dr. Safren also spoke with Dr. Martin Albornoz on the phone in February, 2013 regarding the relatively low number of RVUs that Dr. Safren had produced. In that conversation, Dr. Albornoz told Dr. Safren that Dr. Safren's refusal to bill established patient visits under the

CPT Codes for new patients "didn't help your production numbers." In drawing the contrast between Dr. Safren's billing practices and the practices of the other members of the Maryland Cardiovascular Associates, Dr. Albornoz further confirmed Dr. Safren's understanding that Maryland Cardiovascular Associates physicians other than himself were billing their established patients as new patients for those patients' initial visit after the St. Agnes acquisition.

D. St. Agnes Has Submitted Approximately Six Thousand False Claims to the Medicare System.

53. The Maryland Cardiovascular Associates physicians typically provided outpatient health care services as part of a bi-annual treatment regimen. The fraudulent billing of existing patients as "new patients" by the Maryland Cardiovascular Associates physicians occurred substantially within the first six to eight months of their tenure as employees for St. Agnes, from June 2011 to December 2011.

54. During that period, the physicians in the Maryland Cardiovascular Associates collectively provided health care services to approximately 5,500 to 6,500 existing patients.

E. St. Agnes Submitted False Claims on Behalf of Particular Physicians for Services Provided to Particular Patients.

55. In his capacity as a physician in the Maryland Cardiovascular Associates, Dr. Safren personally saw and treated patients of other doctors in the group. Accordingly, he became aware of particular patients and the treatment they were receiving from particular physicians.

56. Based on his observation, during the period from June to December 2011, St. Agnes fraudulently billed the Medicare program for services provided by the following physicians to the following patients under the billing code for a new patients (codes 99201-99205), when they should have been billed under the billing code for established patients (codes 99211-99215):

Patient	Physician
William Leimkuhler	Dr. Ince
Rene Torregrossa	Dr. Albornoz
Hope Griffin	Dr. Ince
Marie McGinn	Dr. Plantholt

CONCLUSION

57. During the period of June 3, 2011 to December 31, 2011, St. Agnes filed claims on behalf of the eleven physicians identified above, using billing codes 99201-99205, for health care services provided to new patients, when it should have filed those claims using billing codes 99211-99215, for office visits provided to existing patients. It filed those fraudulent claims on behalf of approximately six thousand patients, with the result that the Medicare program paid approximately $1,000,000 to reimburse those false claims. St. Agnes submitted additional such claims to the Federal Employee Health Benefits Program.

58. The claims were improperly filed at the direction of St. Agnes' director of Compliance, and in knowing and/or reckless disregard of the rules governing billing for new patients.

CAUSES OF ACTION

COUNT I
Presentation of False Claims in Violation of 31 U.S.C. § 3729(a)(1)(A)

59. Plaintiff-Relator Dr. Jonathan Safren incorporates by reference the preceding paragraphs as if set forth fully herein.

60. Through the acts described above, St. Agnes knowingly presented false claims for FHIP reimbursements when it billed existing patient visits as new patient visits.

61. St. Agnes knew it was not entitled to bill those visits as new patient visits when it submitted those claims.

62. Every claim that St. Agnes presented for reimbursement of a new patient visit, when the patient had previously seen the same doctor within the last 3 years, was a false claim.

63. Pursuant to 31 U.S.C. § 3729(a)(1), St. Agnes is liable for three times the amount it received as a result of its false claims for Medicare reimbursements from its fraudulent billing of existing patients as new, as well as civil penalties of $5,000 to $11,000 per claim, as adjusted for inflation pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990 and 28 C.F.R. § 85.3.

64. The maximum civil penalties allowed by law are warranted in this case in light of the knowing and systematic violations of the billing requirements for the FHIP.

COUNT II
Creation and Use of False Records or Statements Material to a False Claim in Violation of 31 U.S.C. § 3729(a)(1)(B)

65. Plaintiff-Relator Dr. Jonathan Safren incorporates by reference the preceding paragraphs as if set forth fully herein.

66. Through the acts described above, St. Agnes knowingly made false statements and submitted false billing records for FHIP reimbursement in which it fraudulently characterized existing patients as new patients.

67. Pursuant to 31 U.S.C. § 3729(a)(1), St. Agnes is liable for three times the amount it received as a result of its false claims for Medicare reimbursements from its fraudulent billing of existing patients as new patients, as well as civil penalties of $5,000 to $11,000 per claim, as adjusted for inflation pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990 and 28 C.F.R. § 85.3.

68. The maximum civil penalties allowed by law are warranted in this case in light of the knowing and systematic violations of the Medicare regulations.

REQUESTS FOR RELIEF

WHEREFORE, Plaintiff-Relator Dr. Jonathan Safren requests that the Court enter judgment in his favor and against St. Agnes as follows:

a. That St. Agnes must cease and desist from violating the False Claims Act;

b. That St. Agnes must pay an amount equal to three times the total amount that it knowingly and falsely obtained from fraudulently billing existing patients as new patients;

c. That St. Agnes must pay a civil penalty in the maximum statutory amount of $11,000 for each false claim that St. Agnes submitted to the United States in violation of 31 U.S.C. § 3729(a)(1);

d. That Plaintiff-Relator be awarded the maximum amount allowed pursuant to 31 U.S.C.§ 3730(d);

e. That Plaintiff-Relator be awarded all costs and expenses incurred in bringing this action, including attorney's fees, pursuant to 31 U.S.C. § 3730(d); and

f. That the United States and Dr. Jonathan Safren receive all such other relief as the Court deems just and proper.

JURY REQUEST

Plaintiff-Relator Dr. Jonathan Safren requests a trial by jury for all issues so triable.

Date: July 11, 2016

Respectfully submitted,

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